



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,609	03/05/2002	Adnan M. M. Mjalli	41305/271622	8253

7590 09/09/2004

Cynthia B. Rothschild, Esq.  
Kilpatrick Stockton LLP  
1001 West Fourth Street  
Winston-Salem, NC 27101-2400

EXAMINER

STOCKTON, LAURA

ART UNIT	PAPER NUMBER
----------	--------------

1626

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

10/091,609

## Applicant(s)

M. MJALLI ET AL.

## Examiner

Laura L. Stockton, Ph.D.

## Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 25-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,19-24 and 39 is/are rejected.
- 7) ☒ Claim(s) 3-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

Claims 1-39 are pending in the application.

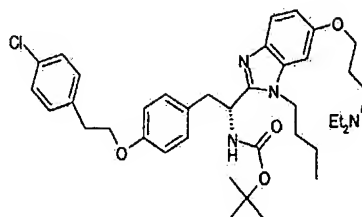
### *Continued Prosecution Application*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on August 25, 2004 has been entered.

### *Election/Restrictions*

Applicants' election of Group I, and the species of Example 9 (shown below), with traverse in the response filed May 7, 2003 was acknowledged in a previous Office Action. The requirement was deemed proper and made FINAL.

**Example 9**



The scope of the elected invention that has been examined, inclusive of the elected species of Example 9, is as follows:

Compounds of Formula (I) where  $R_2$  is definition a) {e.g.,  $R_2$  is a group of the formula  $-N(R_9R_{10})$ ,  $-NHC(O)R_9$  or  $-NHC(O)OR_9$ }.

The scope of the elected invention that has been examined is embraced by claims 1-24 and 39.

Subject matter not embraced by the above identified scope of the elected invention that has been examined and claims 25-38 are withdrawn from further consideration pursuant to 37 CFR

1.142(b) as being drawn to nonelected inventions. Election was made with traverse in the response filed May 7, 2003.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicants' amendment to the claims. Therefore arguments pertaining to these rejections will not be addressed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

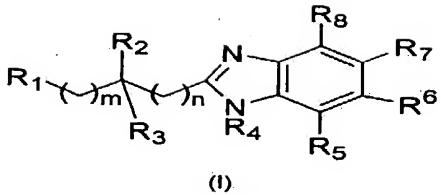
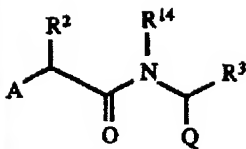
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 19-24 and 39 are rejected under 35

U.S.C. 103(a) as being unpatentable over Xue et al. {U.S. Pat.  
 5,703,092}.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Applicants claim benzimidazole compounds. Xue et al. teach benzimidazole compounds which are structurally similar to the instant claimed compounds (columns 5-8 and 38-41; and especially column 5, lines 35-38 and Example 410 in Table 3 in column 37). See, for example, the comparison table below.

Applicants' compounds	Xue's compounds
<p>Formula (I)</p>  <p>(I)</p>	<p>Formula (I)</p>  <p>Formula I</p>
<p>n is 0;  R<sub>3</sub> is hydrogen</p>	
<p>R<sub>2</sub> is -NHC(O)R<sub>9</sub>;  R<sub>9</sub> is a C<sub>1-6</sub> alkyl substituted with Carboxyl</p>	<p>R<sup>2</sup> is hydrogen;  A is -CH(R<sup>11</sup>)C(R<sup>9</sup>)(R<sup>9a</sup>)CO<sub>2</sub>H;  R<sup>11</sup>, R<sup>9</sup>, R<sup>9a</sup> and R<sup>14</sup> are each hydrogen;</p>

Benzimidazole ring substituted with R <sub>5</sub> , R <sub>6</sub> , R <sub>7</sub> and R <sub>8</sub> on the benzene portion of the ring	Q is a benzimidazole substituted with R <sup>5</sup> ;
R <sub>5</sub> is -Y-C <sub>1-6</sub> alkylene-NR <sub>13</sub> R <sub>14</sub> ; Y is -CH <sub>2</sub> -; R <sub>13</sub> and R <sub>14</sub> are taken together to form a ring (e.g., a piperidine ring); R <sub>6</sub> , R <sub>7</sub> and R <sub>8</sub> are each hydrogen	R <sup>5</sup> is C <sub>1-6</sub> alkyl substituted with R <sup>20</sup> ; R <sup>20</sup> is a heterocycle such as piperidinyl
R <sub>4</sub> is hydrogen	
m is 1; R <sub>1</sub> is aryl	R <sup>3</sup> is a C <sub>1-6</sub> alkyl substituted with R <sup>17b</sup> ; R <sup>17b</sup> is aryl

*Ascertainment of the difference between the prior art and the claims (MPEP*

*§2141.02)*

The difference between compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the

expectation that structurally similar compounds would possess similar activity (e.g., an anti-inflammatory).

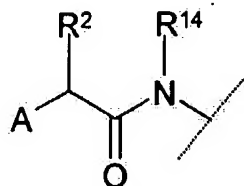
One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful as, for example, an anti-inflammatory. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

### *Response to Arguments*

Applicants' arguments filed August 25, 2004 have been fully considered. Applicants argue that it would not have been obvious to one of ordinary skill in the art to modify the compounds having benzimidazole rings disclosed in Xue et al. to include at least one group of the formula,  $-Y-C_{1-6}\text{alkylene}-NR_{13}R_{14}$ . Specifically,



Applicants argue that: (1) Xue et al. do not describe each and every element of the compounds of Formula (I) in instant claim 1; (2) the compounds of Xue et al. include the amide group



and the amide group in combination with A, R<sup>2</sup>, and R<sup>14</sup> does not describe the R<sub>2</sub> group in the compounds of Formula (I) in claims 1, 2, 19-24 and 39 of the present invention; (3) the difference between the compounds of Xue et al. and the elected species of Example 9; and (4) the amide group in Xue et al. also requires that the A group be terminated with a -COOH or a -CONHOH group whereas the R<sub>2</sub> group in claim 1 of the present application is not terminated with a -COOH or a -CONHOH group.

All of Applicants' arguments have been considered but have not been found persuasive. Xue et al. do teach and suggest the instant claimed compounds. Applicants argue that Xue et al. do not modify their compounds to include at least one group of the

formula,  $-Y-C_{1-6}\text{alkylene}-NR_{13}R_{14}$ . In response, Xue et al. do teach such a group when  $R^5$  is  $C_{1-6}$  alkyl substituted with  $R^{20}$ ;  $R^{20}$  is a heterocycle such as piperidinyl. As shown in the comparison table above, the instant  $R_2$  variable substituents are embraced by Xue et al. when  $R_2$  is  $-NHC(O)R_9$ ;  $R_9$  is a  $C_{1-6}$  alkyl substituted with carboxyl and these definitions correspond to the substituents in Xue et al. when  $R^2$  is hydrogen; A is  $-\text{CH}(R^{11})\text{C}(R^9)(R^{9a})\text{CO}_2\text{H}$ ;  $R^2$ ,  $R^{11}$ ,  $R^9$ ,  $R^{9a}$  and  $R^{14}$  are each hydrogen. Additionally, the elected species of Example 9 is allowable since Xue et al. do not teach or suggest a compound such as instant Example 9. Instant Example 9 (also found in instant claim 11) was never rejected over Xue et al. For all the reasons given above, the instant claimed invention would have been suggested to one skilled in the art and therefore the instant claimed invention would have been obvious to one skilled in the art.

*Allowable Subject Matter*

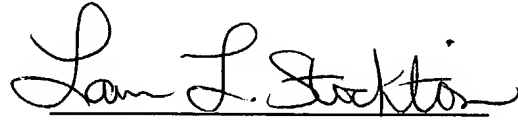
The elected species of Example 9 is allowable over the art of record.

Claims 3-18 are objected to as being dependent upon a rejected base claim, but would be allowable over the art of record if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in cursive script, reading "Laura L. Stockton". The signature is written in black ink and is positioned above the printed name.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

September 7, 2004